

REMARKS

Claims 1-6 and 9-22 are pending in the present application. Claim 8 has been cancelled as the subject matter of claim 8 has been incorporated into claim 1. Claims 1, 4 and 5 have also been amended to provide proper antecedent basis. Claims 1-6 and 9-22 stand rejected under 103(a) as being allegedly rendered obvious by U.S. Patent No. 4,612,923 by Kronenthal ("Kronenthal") in view of U.S. Patent No. 4,743,257 to Tormala ("Tormala"). Claims 1-6 and 9-22 also stand rejected as being allegedly rendered obvious by Tormala in view of Doyle *et al.* (Biomaterials 1991). Applicant traverses these rejections.

Prima Facie Case of Obviousness Has Not Been Made

A. Kronenthal in View of Tormala: There is No Motivation to Combine

The Examiner states it would have been obvious for one of ordinary skill in the art to reinforce the absorbable polymer matrix of Kronenthal by adding a polymeric reinforcing component and further mix a particulate bioglass material because "the '257 [patent] [Tormala] teaches that absorbable polymers typically have lower mechanical strength and that reinforcing the matrix with a polymer improves the initial mechanical strength." Such an analysis fails to appreciate that Kronenthal already provides its own solution to the very problem that the Examiner identified, *i.e.* trying to increase strength of the composite material. There is no motivation to combine the references to solve a problem that has already purportedly been solved by the primary reference.

Specifically, Kronenthal provides a solution to the problem of synthetic absorbable polymers not having adequate mechanical strength (see col. 1, lines 49-53, "the invention provides a means for improving the stiffness and other key mechanical properties of synthetic absorbable polymers. . ") Kronenthal's solution is using an absorbable glass filler to reinforce the polymer and provide a means for stiffening by increasing the polymer's rigidity or column strength (see col. 3, line 62 to col. 4, line 4). Taking the description of the effects of the glass filler on its face, there is no reason for one of ordinary skill in the art to doubt that this approach produces a surgical device that

is sufficiently strong, particularly in view of the results of Example 5, as alleged by Kronenthal. Accordingly, one skilled in the art would not be motivated to add another reinforcement phase to an already reinforced composite material as described by Kronenthal. For at least this reason, one of skill in the art would not be motivated to combine Kronenthal and Tormala to produce the invention as recited in claims 1-6 and 9-22.

B. Tormala in View of Doyle: There is No Motivation to Combine

For similar reasons as discussed below, Applicant submits that there is no motivation to combine Tormala with Doyle because Tormala has already provided its own solution to the problem of lack of mechanical strength. Specifically, Tormala describes a polymeric matrix that is reinforced with reinforcement elements which have the same chemical element percentage composition as does the matrix. According to Tormala "when strong oriented fiber structures are bound together with the polymer matrix which has the same chemical element composition as the fibers, the composite structure is obtained which has excellent adhesion between the matrix and reinforcement material and therefore also has excellent mechanical properties." Col. 3, lines 53-62. Therefore, although the Examiner is correct in noting that the Tormala discusses the strength deficiencies of prior adsorbable polymers, Tormala does so as a prelude to providing a solution to this problem--using oriented fiber structures bound with a polymer matrix that has the same chemical element composition as the fibers. Accordingly, there is no motivation to strengthen the composite material of Tormala with the hydroxyapatite powder of Doyle, since Tormala already describes a composite material that has "excellent mechanical strength properties." Col. 4, line 55-57. Applicant submits that one skilled in the art would have no reason to add a further element to the composite material of Tormala to strengthen an already strong material.

For at least this reason, one of skill in the art would not be motivated to combine Tormala and Doyle to produce the invention as recited in claims 1-6 and 9-22 and Applicant requests withdrawal of this rejection.

C. These Arguments Have Been Presented Before

Applicant points out that similar arguments were presented in the Response to Office Action of June 28, 2004 in which Applicant responded to the Examiner's rejection of the claims as being rendered obvious by Tormala in view of GB 2085461 or GB2085461 in view of Tormala. In that response, Applicant similarly argued that there was no motivation to combine the references because each reference already individually provided its own solution to the very problem that the Examiner identified, i.e. trying to increase the strength of the composite material.

In the present Office Action, the Examiner withdrew this former rejection. Therefore, presumably Applicant's arguments were deemed persuasive. The Examiner has now simply asserted other references in combination with Tormala that are susceptible to the exact same line of argument. Instead of making rejections that are essentially duplicative, Applicant respectfully requests the Examiner to explain why this line of argument is unpersuasive in order to further prosecution. Applicant should not have to respond to the exact same rejection again when such rejection has been adequately addressed once before.

D. References Do Not Teach Each and Every Element of the Claims

Furthermore, even if there were motivation to combine Kronenthal with Tormala, or Tormala with Doyle, Applicant submits that a *prima facie* case of obviousness has still not been made as none of these references teaches a bioglass or bioceramic bioglass reinforcing component having a "particle size between 60 μm and 150 μm ," as recited by the present claims. Kronenthal mentions glass of "very fine particle size" having a diameter of about "2 to 10 microns" which is clearly outside the claimed particle size range. Tormala makes no mention of particle size range. Doyle describes particulate hydroxyapatite powder having a particle size of 8.6 microns, which is also clearly outside the claimed particle size range.

Throughout the prior Office Actions, the Examiner has repeatedly stated that this claimed particle size is "optimizing the particle size" that is within the scope of a skilled artisan. However, there is no teaching in the art that particle size of the bioglass or

bioceramic reinforcing component is a result-effective variable. (See MPEP 2144.05 “[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.”)

For at least these reasons, Applicant submits that claims 1-6 and 9-22 are not rendered obvious by Kronenthal in view of Tormala or Tormala in view of Doyle and therefore these rejections should be withdrawn.

Claimed Particle Range of 60 Microns to 150 Microns is Critical

Even if a *prima facie* case of obviousness has been made (which Applicant clearly does not concede as evidenced by the above arguments), Applicant submits that claims 1-6 and 9-22 are still not rendered obvious by such a combination. Specifically, Applicant submits that the claimed range of particle size of the bioceramic or bioglass reinforcing component of between 60µm and 150µm is critical. Specifically, as Applicant pointed out in the August 25, 2003 Response to Office Action and the June 28, 2004 Response to Office Action, this claimed range achieves unexpected results relative to the prior art.

The specification states at page 6, lines 14-22:

[t]he defined particle size of the ceramic element in the composite described in this invention is relatively big compared to conventionally used particle sizes for fillers or granules. In this invention, it was found unexpectedly that composites having bigger particle size ceramic elements are more biocompatible and cause less irritation to tissue than composites utilizing a ceramic element having small particle size. Biocompatibility is easily seen in histological studies. In tissue near and inside the degrading composite implants having small ceramic particles there exists more giant cells than around and inside the degrading composite implants containing big (coarser) ceramic particles.

The increased biocompatibility seen with coarser particles is supported by Example 11 of the present specification which compares histological studies of composite plates with finer hydroxyapatite powder (7.43 microns) and coarser hydroxyapatite particles (80 +/- 20 microns). As shown in Example 11:

in histological studies it was clearly seen, that in and around the composite plates with finer hydroxyapatite powder [7.43 microns] there existed significantly more giant cells than in the tissue of reference animals containing composite plates with

coarser hydroxyapatite particles [80 +/- 20 microns]. Thus, coarser hydroxyapatite particles were shown to be more biocompatible.

Page 13, lines 18-23.

Applicant has therefore shown that the claimed particle size of 60 μm to 150 μm of the bioglass or bioceramic reinforcing component is contrary to conventional practice and renders unexpected benefits, such as greater biocompatibility and less irritation to tissue. For at least this reason, Applicant submits that claims 1-6 and 9-22 are not rendered obvious by Kronenthal in view of Tormala or Tormala in view of Doyle.

Applicant again points out that this line of argument was set forth in the last two responses filed by Applicant and the Examiner has yet to address this point.

As stated by the MPEP, “[o]ffice personnel should consider all rebuttal arguments and evidence presented by applicants.” (MPEP 2144.08(II)(B)). Therefore, Applicant respectfully requests that the Examiner specifically address why Applicant’s evidence of unexpected results is in any way insufficient. Otherwise, the obviousness rejections should be withdrawn.

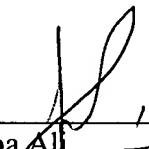
CONCLUSION

Applicant submits that the subject application is in condition for allowance, and respectfully requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON

Date: 10/25/04



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